UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,916	09/22/2003	Feng Hong	200144.407	1925

500 7590 04/05/2004

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
AULAKH, CHARANJIT	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,916	HONG ET AL.	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *3/31/04* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-59 are pending in the application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-59, drawn to compounds of formula of claim 1 where Y represents N and both X and Z represent CH or CR, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 312.

II. Claims 1-59, drawn to compounds of formula of claim 1 other than defined above for group I, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 1+.

3. The inventions I and II as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of invention II prima facia obvious. Search required for e.g ; compounds of invention I in class 546 is not the same search required for e.g ; compounds of invention II in class 544 and therefore, constitutes a burdensome search.

4. During a telephone conversation with the applicant's attorney, Mr. Richard G. Sharkey on March 31, 2004, a provisional election was made with traverse to prosecute the invention of group I (compound 12 in table 1 as species), claims 1-59. Affirmation of this election must be made by applicant in replying to this Office action. It

is of note that group II is subject to further restriction based on the values of variables X, Y and Z in the future applications.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858. F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast

five of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art and the breadth of claims.

The instant compounds are inhibitors of the activity of LPAAT-beta as shown in table 1 on pages 32 and 33 and therefore, will have utility in treating disease conditions where LPAAT-beta inhibitors have been shown to have utility in the prior art or alternatively where LPAAT-beta inhibitors have been shown to be efficacious in known animal models of specific disease conditions. In the instant specification, there is no teaching regarding either known utility of LPAAT-beta inhibitors in the prior art or their efficacy in any known animal models of disease conditions. There are no working examples present to show the efficacy of instant compounds in known animal models of any disease condition. The instant compounds of formula of claim 1 encompasses hundreds of thousands of compounds based on the values of variables R, R1-R6 and Q and therefore, in absence of such teachings, guidance or presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of various disease conditions or cancel cell lines and hence their utility.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, the value of variables R4, R5 and R6 defined as heterocycle is indefinite since the size of the ring, number and types of heteroatoms present are not defined. Also, their value is defined as N3. Is it correct ?

Claims 9, 18, 29, 40, 50 and 59 depend directly or indirectly upon claim 1 and refer to any one of compounds 1-14 of table 1. However, table 1 is neither present in claim 1 nor in these claims. The applicants are suggested to include the specific compounds in these claims which read upon the elected group.

In claim 19, the term –reducing --- is indefinite since the degree of reduction is not defined. Is it reduced by 20%, 50% or 100% ? Also, is directed to in vitro method or in vivo method ? In addition, where the activity of LPAAT-beta is being reduced. Is it in plasma, some specific tissue such as brain, spinal cord, gut, heart etc. and furthermore, what is the end result for reducing activity. Does it help in treating some disease condition ? If so, the applicants are suggested to include the specific disease condition to be treated by reducing activity of LPAAT-beta in the claim.

In claims 20 and 31, the term ---resides--- is indefinite since the specific location is not defined. Is it plasma, blood or some specific tissue ?

In claim 30, the term –inhibiting --- is indefinite since the degree of inhibition is not defined. Is it inhibited by 20%, 50% or 100% ? Also, is directed to in vitro method or in vivo method ? In addition, the type of cell is not defined. Is the cell from a normal

tissue or specific cancerous tissue ? and furthermore, what is the end result for inhibiting proliferation. Does it help in treating some disease condition ? If so, the applicants are suggested to include the specific disease condition to be treated by inhibiting proliferation of specific tissue cell type in the claim.

In claim 41, the term ---cancer--- is indefinite since the specific type of cancerous tissue associated with activity of LPAAT-beta is not defined. Also, is the cancer associated with an increased activity or decreased activity of LPAAT-beta ? The applicants are suggested to include only specific tissues for treating which meet the enablement requirement.

In claim 42, the applicants are suggested to either delete this claim or change animal to mammal in claim 41 and then change the language of claim 42 to read – wherein the mammal is an animal – since animal can not be anything else except mammal whereas mammal can be a human also in addition to an animal.

In claim 51, the term –inhibiting --- is indefinite since the degree of inhibition is not defined. Is it inhibited by 20%, 50% or 100% ? Also, is directed to in vitro method or in vivo method ? In addition, the type of cell is not defined. Is the cell from a normal tissue or specific cancerous tissue ? and furthermore, what is the end result for inhibiting proliferation. Does it help in treating some disease condition ? If so, the applicants are suggested to include the specific disease condition to be treated by inhibiting proliferation of specific tissue cell type in the claim.

In claim 51, the term –coated medical device—is indefinite since the type of device is not defined. Is it some type of instrument? The applicants are suggested to be specific to the type of device supported by the instant specification.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 8, 10-12, 17, 30-34, 39, 41-44, 49, 51-53 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmermann (Arch. Pharm. Pharm. Med. Chem.).

Zimmermann discloses Phenylamino-pyrimidine (PAP) derivatives having antiproliferative effect on human bladder carcinoma cells. The compounds 37 and 38 (page 373) disclosed by Zimmermann anticipate the instant claims when Q represents –NH, R1 and R2 are H and R5 represents Cl in the instant compounds of formula of claim 1.

11. Claims 1, 2, 8, 10, 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Haviv (J. Med. Chem.).

Haviv discloses 2-[(Phenylthio)pyridine derivatives having anti-inflammatory activity. The compound 2J (see table II on page 219) disclosed by Haviv anticipates the instant claims when Q represents –CH2S, R1, R2 and R3 represent H and R4 represents Br in the instant compounds of formula of claim 1.

12. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by compound, RN 19933-09-6.

The compound, RN 19933-09-6 is disclosed in an article published in journal, Gazzeta Chimica Italiana, vol. 98 (5), pages 511-534, 1968. This compound anticipates the instant claims when Q represents –NH and R1-R5 are H in the instant compounds of formula of claim 1.

13. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by compound, RN 34891-38-8.

The compound, RN 34891-38-8 is disclosed in an article published in a Russian journal, Khimiya Geterotsiklicheskikh in 1971. This compound anticipates the instant claims when Q represents –CH2O and R represents methyl in the instant compounds of formula of claim 1.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by compound, RN 54396-39-2.

The compound, RN 54396-39-2 is disclosed in WO 2003/ 049702 published on 19 June, 2003 having filing date of Dec. 10, 2002. The compound, RN 54396-39-2 anticipates the instant claims when Q represents –NH and R4 and R5 together with the benzene ring form a heterocycle in the instant compounds of formula of claim 1.

15. Claims 1-59 are objected as containing non-elected subject matter.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

C. S. Aulakh

Charanjit S. Aulakh
Primary Examiner
Art Unit 1625